K130682

510(k) Traditional
Meisinger Tacs and Pins

Section #5

510(k) Summary

AUG 13 2013

Name of Submitter:	Hager & Meisinger GmbH Hansemannstraße 10 41468 Neuss, Germany Phone: (0049) 2131 2012-0 Fax: (0049) 2131 2012- 222
Contact Person:	Wiebke Stolten Management product approval and product validation (Regulatory Affairs) wiebke.stolten@meisinger.de
Date Prepared:	04/26/2013
Trade Name:	Meisinger MEITAC, Meisinger Master-Pin-Control
Common Name:	Tacs (MEITAC- Kit), Pins (Master-Pin-Control-Kit)
Classification Name:	Screw, Fixation, Intraosseous
Product Code:	DZL
Regulation No:	872.4880
Class:	II
Panel:	Dental
Predicate Devices:	K092855 Miltex® Membrane Tack Kit K973180 IMTEC Bone Tac
Device Description:	The Meisinger Tacs and Pins consist of titanium alloy Grade 5. The Meisinger Pins are a Tac-equivalent with an extra mini- thread. Both articles are available with a head diameter of 2.51 mm, the Pin is available with overall length of 3.65mm (pin length 2.65mm) and the Tac with a length of 3.5mm (2.8mm) Tacs and Pins are delivered non sterile.

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Intended Use:	Tacs and Pins are used for the fixation of membranes (resorbable membranes non-resorbable membranes) to the bone structure. Tacs and Pins are intended for single use only.
Technological Characteristics:	The Meisinger Tacs and Pins have the same intended use and are substantially equivalent to the legally marketed predicate devices in the United States. The screws use the same biocompatible materials meeting the requirements from ASTM F136 as the predicated devices. The design is similar, at least equivalent to predicated devices: All products have comparable dimensions and design and the intended use is equivalent.
Clinical Testing:	Not applicable
Conclusion:	The function and intended use, material, possible product have been evaluated as acceptable and equivalent to predicated devices. Based on the information provided in the summary we conclude that the Meisinger Tacs and Pins are substantially equivalent to the legally marketed predicate devices described.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 13, 2013

Hager & Meisinger GmbH
Mr. Wiebke Stolten
Management Regulatory Affairs
Hansemannstraße 10
Neuss, Germany 41468

Re: K130682
Trade/Device Name: Meisinger Tacs and Pins
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: July 12, 2013
Received: July 16, 2013

Dear Mr. Stolten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130682

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Meisinger Tacs and Pins K130682

Section #4

Indications for Use Statement

510(k) Number (if known): K130682

Device Name: Meisinger Tacs and Pins

Indications for use:

Tacs and Pins are used for the fixation of membranes (resorbable membranes non-resorbable membranes) to the bone structure.

Tacs and Pins are intended for single use only.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2013.08.07 15:36:42 -04'00'

for M. Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130682